REMARKS

This Amendment is responsive to the non-final Office Action of September 24, 2008. Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

I. Status of Claims

Claims 22-43 were pending in the application. Of these, claims 24-43 were withdrawn, and claims 22 and 23 were rejected. Claim 22 and 23 have been amended to clarify the invention and new claims 44-50 have been presented. No new matter is added.

II. Restriction/Election Requirement

The office action notes at page 4 that "[c]laims 24-43 are withdrawn from further consideration" and "the restriction requirement is still deemed proper and is therefore made FINAL." Applicant respectfully requests reconsideration of the restriction requirement.

III. Rejections Under 35 U.S.C. §112, First Paragraph, Enablement

Claims 22-23 stood rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to satisfy the enablement requirement based on various assertions made at pages 5-8 of the Office Action. Applicant respectfully traverses this rejection.

The Examiner asserts, among other things, that:

> "[t]he specifications teaching is limited to lowering cholesterol, lowering triacylglycerols in the liver, decreasing the activity of Acyl-coA:cholesterol acyltransferase (ACAT) and increasing mitochondrial beta-oxidation in obese Zucker rats . . . the single cell protein material combination from *Methylococcus capsulatus*, *Ralstonia* sp., *Brevibacillus agri* and *Aneurinibacillus* sp lowered cholesterol in these animals but the specification does not teach whether these mice had abnormal levels of cholesterol and triacylglycerol in the first place. Therefore, it is not clear whether the administered composition was lowering cholesterol and triacylglycerol from high levels to normal levels. Thus, it cannot be determined whether the composition administered was treating any disease in these mice and it is therefore unpredictable that the effects of the administered composition in these mice correlates

> with treatment of any disease in any subject. Also, the specification does not correlate the effects of administering any single cell protein material to any animal model of disease with prevention of the onset of the disease in said animal model."

The Examiner also contends, citing Vaskonen et al., 2002, J. Nutr. 132:231-237, that:

> "the obese Zucker rat model used in the experiments in the specification is not a suitable model for atherosclerosis and the specification does not teach whether any 'human like' conditions were induced in these mice to make them more suitable for studies on atherosclerosis, other cardiovascular diseases and risk factors for these diseases."

Applicant respectfully submits that the animal model used for demonstrating treatment or prevention of atherosclerosis or coronary heart disease in the instant application is a suitable animal model for these diseases. Applicant notes Vaskonen's teachings at page 231, column 2, second full paragraph. That paragraph also teaches that hypercholesterolemia can be induced in obese Zucker rats by increasing the dietary intake of saturated fat and cholesterol. At page 232, left column, Vaskonen provides a table listing compositions of the different diets. When these compositions are compared with the composition of the experimental diets listed in Table 1 at page 11 of the instant application, the amount of fat fed to the rats is twice as much that normally recommended for rats or the control diet disclosed in Vaskonen.

As can be seen from the data in the present application, the rats fed with casein containing (i.e., non single cell protein material or SCP) composition showed several fold high levels of cholesterol in plasma and triacyl glycerols in liver. Because the amount of fat fed to the Zuker rats is two fold more than that normally recommended for rats, one skilled in the art would know that cholesterol in plasma and triacyl glycerols in liver are high levels which were brought to normal levels in the rats fed with SCP containing composition.

Additionally, the specification must be enabling only to a person skilled in the art. In view of the acknowledged high level of skill required in the field, the experimentation, if any, that might be required to practice Applicant's invention in a particular setting would be of the kind normally carried out by skilled artisans in the field. In the present case, those skilled in the art can in fact reasonably expect that the Zucker rat model used is a suitable animal model for demonstrating treatment or prevention of atherosclerosis or coronary heart disease, and mimics the situation in other animals, for example, human. Indeed, those skilled in the art

would have successfully determined any other parameters or variables necessary for inducing even higher levels of cholesterol and triacyl glycerols than those induced in the animal models based on the extensive data and the Examples in the application. Such findings would not place an undue burden on one skilled in the art, since it can be determined by routine and reasonable experimentation. Therefore, one reasonably skilled in the art could make and use the invention from the disclosures in the application coupled with information known in the art without undue experimentation.

Furthermore, Applicant believes that the current amendments further clarify the claimed invention, and obviate this rejection. Unless evidence is provided to the contrary showing that the specification does not sufficiently disclose the invention, as presently claimed, so that one skilled in the art could not have practiced the claimed invention without resorting to undue experimentation, Applicant respectfully submits that a *prima facie* case of non-enablement has not been made.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph as it might be applied to the revised claim 22-23 and/or the new claims 44-50 presented herein.

IV. Rejections Under 35 USC § 102

Pang

Claims 22-23 stood rejected under 35 U.S.C. § 102(b) as being anticipated by Pang *et al.* (WO 02/34273) ("Pang"). This rejection is respectfully traversed and believed to be overcome in view of the following discussion:

Claim 22, which is an independent claim, is directed to a method of treating or preventing atherosclerosis or coronary heart disease in an animal in need of such treatment by administering a pharmaceutical or nutritional composition containing a single cell protein material harvested from a micorbial culture containing *Methylococcus* bacteria.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Schering Corporation v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003). Identity of invention requires that a prior reference disclose to one of ordinary skill in the art all elements and limitations of the patent claim. *Scripps Clinic v. Genentech*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible, Inc.*, 230 USPQ 81 (Fed. Cir. 1986). Inherent anticipation requires that the missing descriptive material is "necessarily present," not merely, probably or

possibly present in the prior art reference. *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999). In general, a limitation or the entire claimed invention is inherent and in the public domain if it is the "natural result flowing from" the explicit disclosure of the prior art. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001). To anticipate, the reference must also enable one of ordinary skill in the art to make and use the claimed invention. *In re Donohue,* 766 F.2d 531, (Fed. Cir. 1985).

The Examiner cites Pang as teaching "a method of treating or preventing cardiovascular disorders such as coronary heart disease/atherosclerosis, atheroma, disorder to an animal a pharmaceutical or nutritional composition (e.g. yoghurt or soy) comprising yeast or bacteria. The Examiner cites to "p. 4 lines 9-19, p. 5 lines 7-16, p. 7 lines 19-25 to p. 8 lines 1-3, p. 9 lines 6-7, p. 12 lines 15-19, p. 14 - p. 16 and figure 5" of the Pang reference. The teachings in these specifically cited portions of Pang relate to, among other things, upregulating a Th1 T-cell response using food products like yogurt containing microorganisms, particularly probiotic bacteria *Lactobacillus spp.*, and/or *Mycobacterium spp.*, in connection with cardivascular disorders including atherosclerosis.

Pang does not teach, however, either expressly or inherently, the method in claim 22. For example, Pang does not teach, either expressly or inherently, a pharmaceutical or nutritional composition containing a single cell protein material harvested from a micorbial culture containing *Methylococcus* bacteria. Pang is completely silent as to the requirement that the single cell protein material contain high proportions of proteins. Additionally, since anticipation requires that each and every limitation of a claim be found either expressly or inherently in a single prior art reference, Pang fails to anticipate the claimed invention.

To anticipate, the cited reference must also enable one of ordinary skill in the art to make and use the claimed invention. The present application describes the claimed invention in detail including extensive experimental data showing that the material lowers the concentration of plasma cholesterol, decreases the concentration of triacylglycerols in liver, inhibits the activity of Acyl-CoA, increases the mitochondrial β-oxidation, interfere with the PPARs, and lowers the concentration of plasma homocystein. This sort of enabling information is absent in Pang.

As such, given the strict identity required of the test for novelty, the Examiner has not established a *prima facie* case of anticipation in support of the rejection of claim 22. Further, the rejected dependent claim 23 and the newly added claims 44-50 are similarly considered by Applicant to patentably define themselves over the Pang reference by virtue of their

dependency from the independent claim. Reconsideration and withdrawal of the rejection are respectfully requested.

Pedraglio

Claim 22 stood rejected under 35 U.S.C. § 102(b) as being anticipated by Pedraglio *et al.* (EP 0861905) ("Pedraglio"). Applicant respectfully traverses this rejection.

Claim 22 and the applicable law are discussed above.

The Examiner contends that "Pedraglio et al teach a method of treating (therapeutic) or preventing (prophylactic) a gastrointestinal disorders (diarrhea, colitis, gastroenteritis etc) of human (animal) comprising administering to said human (animal) a pharmaceutical or nutritional composition (milk or yogurt) comprising *Lactobacilli* (single cell microorganism). See abstract, p. 5 lines 9-12, 32-58, p. 6 lines -14."

As noted above, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. As conceded by the Examiner, Pedraglio's compositions contain *Lactobacilli.* Pedraglio does not teach, however, either expressly or inherently, the method in claim 22. For example, Pedraglio does not teach, either expressly or inherently, a pharmaceutical or nutritional composition containing a single cell protein material harvested from a micorbial culture containing *Methylococcus* bacteria. Pedraglio is completely silent as to the single cell protein material contain high proportions of proteins. Since anticipation requires that each and every limitation of a claim be found either expressly or inherently in a single prior art reference, Pedraglio fails to anticipate the claimed invention.

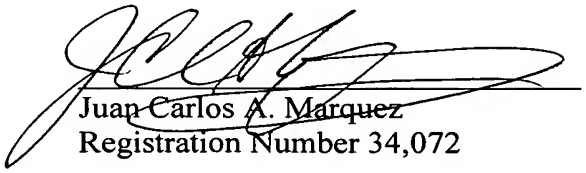
As such, the Examiner has not established a *prima facie* case of anticipation in support of the rejection of claim 22 based on Pedraglio. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. § 102 (b) are respectfully requested.

V. Conclusion

Applicant believes this response to be a full and complete response to the Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the present application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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